

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION**

OUTSOURCING FACILITIES
ASSOCIATION; NORTH AMERICAN
CUSTOM LABORATORIES, LLC, d/b/a
FARMAKEIO SUPERIOR CUSTOM
COMPOUNDING, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, and SARA BRENNER,
in her official capacity as Acting
Commissioner of Food and Drugs,

Defendants.

Case No. 4:25-cv-00174-P

**BRIEF IN SUPPORT OF
NOVO NORDISK INC.'S MOTION TO INTERVENE**

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INTRODUCTION

Novo Nordisk Inc. (“Novo Nordisk”) meets the requirements for intervention as of right pursuant to Federal Rule of Civil Procedure 24(a)(2). Novo Nordisk has a direct and concrete stake in the outcome of this litigation. Plaintiffs have challenged FDA’s removal of Novo Nordisk’s FDA-approved semaglutide injection medicines from FDA’s drug shortage list. Novo Nordisk is the only company that markets FDA-approved semaglutide injection medicines—Ozempic® and Wegovy®. Novo Nordisk would be harmed significantly if Plaintiffs succeeded in delaying or reversing FDA’s well-supported decision.

If Novo Nordisk’s FDA-approved semaglutide injection medicines were to be placed back on the shortage list, Novo Nordisk and the public health would be harmed in several ways. *First*, the well-recognized safety and efficacy risks associated with non-approved compounded “semaglutide” drugs pose risks to Novo Nordisk’s reputation. Patients often wrongly associate these compounded products with Novo Nordisk, and so incorrectly attribute quality problems and harms from ineffective or unsafe compounded products to Novo Nordisk. *Second*, the continued manufacture and sale of these riskier, non-approved compounded products undermine the investments that Novo Nordisk has made in bringing to market its safe and effective FDA-approved medicines, including investments to market to and supply the U.S. market.

Novo Nordisk therefore moves to intervene in this action to defend its legally protectable interests. As in *OFA v. FDA*, No. 4:24-cv-00953-P (N.D. Tex.), Novo Nordisk satisfies all of Rule 24(a)’s requirements for intervention.

Novo Nordisk's motion is timely—filed only seven days after the complaint was filed—and Novo Nordisk agrees to observe any schedule for pleadings and other briefing the Court enters. *See Fed. R. Civ. P. 24(a)(2).*

Novo Nordisk has a clear and substantial interest “relating to the property or transaction that is the subject of the action.” *Id.* Plaintiffs challenge a regulatory framework and determination that ensure (when enforced): (a) that patients receive medicines that FDA has determined are safe and effective; and (b) that Novo Nordisk has a statutorily-conferred ability to market and sell its FDA-approved medicines without competition from compounders offering unapproved and unsafe compounded drugs. *Id.*

FDA—a government agency tasked with administering the policy goals and objectives of the federal government—cannot adequately represent Novo Nordisk's commercial interests, including the need to protect the confidentiality of Novo Nordisk's commercially sensitive information and Novo Nordisk's interest in protecting the significant investments necessary to bring to market safe, FDA-approved medicines. And FDA may not agree with Novo Nordisk's interpretation of Section 503A of the FDCA. Novo Nordisk should be allowed to intervene to protect its interest in seeing the appropriate application of Section 503A for semaglutide injection medicines.

Alternatively, Novo Nordisk meets the standard for permissive intervention under Rule 24(b) because intervention at this early stage in the litigation will not unduly delay proceedings or prejudice the parties, and the presented questions of law

and fact—whether FDA lawfully removed semaglutide injection medicines from the drug shortage list—are common to the defenses of Novo Nordisk and the federal defendants.

BACKGROUND

A. Novo Nordisk and Semaglutide Injection Medicines

Novo Nordisk is a leading healthcare company that markets medicines to treat patients with serious chronic diseases like diabetes, obesity, kidney disease, and cardiovascular disease. Novo Nordisk is the only company that offers FDA-approved medicines containing semaglutide, a glucagon-like peptide-1 receptor agonist, which is marketed in an injectable form under the trade names Ozempic® and Wegovy®. The FDA first approved Ozempic® in December 2017 and Wegovy® in June 2021.¹ Ozempic® and Wegovy® are the only “two injectable semaglutide products FDA-approved for the U.S. market.”² Ozempic® is currently indicated for several uses, including use “to improve glycemic control in adults with type 2 diabetes,” “to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease,” and to reduce the risk of “end-stage kidney disease and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.”³ Wegovy® is currently indicated for several uses, including use “to reduce the risk of major adverse cardiovascular events ... in adults with

¹ See FDA, [NDA Approval Letter for NDA 209637](#) (Dec. 5, 2017) (Ozempic®); FDA, [NDA Approval Letter for NDA 215256](#) (June 4, 2021) (Wegovy®).

² FDA, [Approved Label for NDA 209367](#) (Jan. 28, 2025); FDA, [Approved Label for NDA 215256](#) (Nov. 1, 2024).

³ *Approved Label for NDA 209367, supra* n.2.

established cardiovascular disease” and “to reduce excess body weight” in children and adults ages twelve and older.⁴

To obtain FDA approval to manufacture and sell Ozempic® and Wegovy®, the drugs underwent a long, comprehensive, and costly testing process that required demonstrating that there was sufficient “information to determine whether” Ozempic® and Wegovy® are “safe for use” under the proposed conditions of use, and “substantial evidence that the drug[s] will have the effect [they] purport[] or [are] represented to have.” 21 U.S.C. § 355(d)(4)–(5); *see also* 21 C.F.R. § 314.125(b). FDA’s approval process included a rigorous examination of “the methods used in, and the facilities and controls used for, the manufacture, processing, and packing” of a drug, which are the methods, facilities, and controls of the approved manufacturer. 21 U.S.C. § 355(b)(1)(A)(iv). For example, to obtain FDA approval for Novo Nordisk’s semaglutide injection medicines, Ozempic® and Wegovy®, the drugs were subject to “more than 100 phase II and III clinical trials … over the course of more than three decades, collecting more than 135,000 person-years of data.”⁵ By one “conservative” estimate, development of these medicines cost “well over \$10 billion” in research and development.⁶

⁴ *Approved Label for NDA 215256, supra* n.2.

⁵ *See Testimony of Lars Fruergaard Jørgensen, Hearing before the S. Comm. on Health, Educ., Labor and Pension, at 11, 118th Cong. (Sept. 24, 2024).*

⁶ *See id.*

B. The FDCA Provisions Governing Compounding and the Drug Shortage List

The status of Novo Nordisk's FDA-approved semaglutide injection medicines on the drug shortage list under Section 506E of the Federal Food, Drug, and Cosmetic Act ("FDCA") affects compounders' ability to compound "semaglutide" injection products under FDCA Section 503A (as interpreted by FDA in guidance) and the statutory language of FDCA Section 503B.

FDCA Section 506E provides: "The Secretary shall maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States." 21 U.S.C. § 356e(a). For each drug on the list, the Secretary must include, among other things, "the reason for the shortage," based on the following categories: (a) requirements related to complying with good manufacturing practices; (b) regulatory delay; (c) shortage of an active ingredient; (d) shortage of an inactive ingredient component; (e) discontinuance of the manufacture of the drug; (f) delay in shipping of the drug; and (g) demand increase for the drug. *Id.* § 356e(b)(3). Section 506E does not make any reference to Sections 503A or 503B, or otherwise mention drug compounding.

Under Section 503A, drug products compounded by licensed pharmacists and physicians are eligible for exemptions from key requirements applicable to prescription drugs, including premarket approval, adequate directions for use in labeling, and current good manufacturing practice requirements when they meet certain requirements. 21 U.S.C. § 353a(a). Section 503A additionally requires a licensed pharmacist or licensed physician "not [to] compound regularly or in

inordinate amounts ... any drug products that are *essentially copies of a commercially available drug product.*⁷ *Id.* § 353a(b)(1)(D) (emphasis added). FDA has interpreted in guidance that a drug will not be considered commercially available if the drug product appears on the 506E drug shortage list.⁸ Thus, if Novo Nordisk's FDA-approved semaglutide injection medicines were listed as "in shortage" on the drug shortage list, FDA would not consider Ozempic® and Wegovy® to be "commercially available" within the meaning of Section 503A, potentially allowing 503A compounders to compound these drugs without regard to the "essentially a copy" restriction.

Under Section 503B, drug products compounded by outsourcing facilities are eligible for exemptions from FDA premarket approval, adequate directions for use in labeling, and drug supply chain security requirements when they meet certain requirements. 21 U.S.C. § 353b(a). These conditions include, among other things, that "the drug is not essentially a copy of one or more approved drugs." *Id.* § 353b(a)(5). Section 503B(d)(2) provides that the term "essentially a copy of an approved drug"

⁷ Under Section 503A, entitled "Pharmacy compounding," pharmacies may "compound" *limited* quantities of drugs "for an identified individual patient based" on a physician's determination "that a compounded product is necessary for the identified patient," 21 U.S.C. § 353a(a), such as when a patient is allergic to an ingredient in the approved drug. *See Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 387 (5th Cir. 2008).

⁸ FDA, [Guidance for Industry: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act](#), at 5 (Jan. 2018). While Novo Nordisk does not agree with FDA's interpretation that a drug will not be considered commercially available if the drug product appears on the 506E drug shortage list, FDA's position is laid out here for purposes of argument.

means “a drug that is identical or nearly identical to an approved drug, ... *unless, in the case of an approved drug, the drug appears on the drug shortage list* in effect under Section 506E of this title at the time of compounding, distribution, and dispensing.” *Id.* § 353b(d)(2)(A) (emphasis added). Section 503B(a)(2) also references the drug shortage list under Section 506E, stating that compounding drugs using bulk drug substances is permitted if “the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E of this title at the time of compounding, distribution, and dispensing.” *Id.* § 353b(a)(2)(A)(ii).

C. Compounded Drugs Pose Distinct Safety Risks

Since compounded drugs are not approved by FDA, compounders purport to rely on 503A and 503B to make “an end-run around” the FDA’s new drug approval process. *Mukasey*, 536 F.3d at 390. The lack of FDA approval for compounded drugs “means that FDA does not review these drugs to evaluate their safety, effectiveness or quality before they reach patients.”⁹ Because compounded drugs do not have these same “assurances as approved drugs,” FDA recommends that compounded drugs “only be used for patients whose medical needs cannot be met by an available FDA-approved drug.”¹⁰ In addition, FDA has warned that, because they are not FDA-

⁹ FDA, [Human Drug Compounding Laws](#) (Dec. 17, 2024).

¹⁰ FDA, [Compounding and the FDA: Questions and Answers](#) (Nov. 15, 2024); FDA, [FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products](#) (July 26, 2024).

approved, “compounded drugs may expose patients to potentially serious health risks” including “serious patient injury and death.”¹¹

These concerns are particularly acute with respect to compounded “semaglutide” injection products, because the process used to produce most “semaglutide” used in compounding is fundamentally different from the process used to produce the semaglutide in Novo Nordisk’s FDA-approved medicines. Pursuant to its FDA approval, Novo Nordisk manufactures the semaglutide in its medicines in yeast cells under a closely controlled multi-step process that uses recombinant DNA technology. Most compounded knockoff semaglutide injection products, however, use a form of semaglutide manufactured via chemical synthesis. The fundamental differences between these processes have resulted in new impurities, higher levels of known impurities, immunogenicity concerns, and potential stability issues in tested samples of *compounded* “semaglutide.”¹²

Compounded “semaglutide” injection “may [also] contain too much or too little of the active ingredient, contain the wrong ingredients altogether, or even contain harmful substances.”¹³ FDA has issued guidance on its “Concerns with Unapproved GLP-1 Drugs Used for Weight Loss,” which explains that: (1) “compounded drugs are not FDA approved”; (2) use of compounded drugs containing semaglutide “can be

¹¹ *Compounding and the FDA: Questions and Answers*, *supra* n.10.

¹² Morten Hach *et al.*, *Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs*, Pharm. Res. (Oct. 8, 2024).

¹³ FDA, *Navigating the World of Online Pharmacies with CDR Lysette Deshields* (Mar. 7, 2024).

risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness, and quality"; and (3) "FDA has received reports of adverse events related to compounded versions of semaglutide.... However, [because] federal law does not require state-licensed pharmacies that are not outsourcing facilities to submit adverse events to FDA[,] ... it is likely that adverse events from compounded versions of these drugs are underreported."¹⁴

Plaintiffs seek to maintain a "shortage" so that they may continue to produce unsafe, unapproved purported knockoffs of FDA-approved semaglutide medicines.

D. FDA-Approved Semaglutide Injection Medicines and the Drug Shortage List

Ozempic® and Wegovy® are sought-after and widely used medications that have achieved name-brand recognition across the United States. In 2022, FDA identified "semaglutide injection"—a category that consists of Ozempic® and Wegovy®—as "Currently in Shortage" in its FDA drug shortage database.¹⁵ The shortage of Novo Nordisk's FDA-approved semaglutide injection medicines has since resolved. On February 21, 2025, FDA removed Ozempic® and Wegovy® from the drug shortage list based on its determination that the "demand or projected demand" for each of these medicines no longer "exceed[ed] the supply of the drug." FDA

¹⁴ FDA, [*FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss*](#) (Dec. 18, 2024).

¹⁵ On March 31, 2022, FDA identified Wegovy® "Currently in Shortage" in its drug shortage database, and did the same for Ozempic® on August 23, 2022.

Declaratory Order¹⁶ at 1; *see also* 21 U.S.C. § 356c(h)(2). Specifically, FDA found that Novo Nordisk submitted “detailed information and data regarding Novo Nordisk’s production and inventory of these drug products, such as quantities supplied and demanded, and inventory held in stock, for all strengths of these medicines; projected supply and demand in future months; and wholesaler inventory data.” FDA Declaratory Order at 1–2. FDA also “considered information from multiple sources other than Novo Nordisk, including telehealth companies, pharmacy compounders, associations representing pharmacy compounders and outsourcing facilities, and individuals” in making its determination. *Id.* at 2. FDA noted that this second category of information “has important limitations” and “does not undermine or outweigh the evidence demonstrating that Novo Nordisk’s supply is currently meeting or exceeding demand.” *Id.* And, despite reports that “some patients and pharmacists are not able to obtain the approved drugs,” that is “most likely explained not by a continuing national shortage of supply, but by the practical dynamics of the part of the supply chain between Novo Nordisk and [its] customers, including wholesale distributors and pharmacies.” *Id.* Based on the extensive information that it reviewed, FDA determined that the shortage of semaglutide injection medicines is “resolved.” *Id.* at 1.

¹⁶ FDA, [Declaratory Order: Resolution of Shortages of Semaglutide Injection Products \(Ozempic and Wegovy\)](#) (Feb. 21, 2025).

In other words, there is no need for patients to resort to risky, unapproved knockoffs of Ozempic® and Wegovy®—Novo Nordisk can furnish FDA-approved semaglutide injection medicines at a quantity exceeding demand.

On February 24, 2025, Plaintiffs Outsourcing Facilities Association (“OFA”) and Northern American Custom Laboratories, LLC (“FarmaKeio”) filed suit for declaratory and injunctive relief, challenging FDA’s removal of semaglutide injection medicines from the drug shortage list. *See* Compl. ¶¶ 2–3 (ECF No. 1). OFA alleges that its members are outsourcing facilities that engage in compounding; FarmaKeio alleges that it is a pharmacy that engages in drug compounding. Plaintiffs want to keep compounding “semaglutide” products notwithstanding the resolution of the shortage and the risks that such knockoff drugs pose to patients. Their activities pose a reputational risk to Novo Nordisk’s FDA-approved medicines, and in turn to Novo Nordisk, and undercut Novo Nordisk’s and its affiliates’ recoupment of the massive costs associated with developing, safely manufacturing, and bringing to market FDA-approved drugs.

To protect its interests, Novo Nordisk moves to intervene.

ARGUMENT

I. Novo Nordisk is entitled to intervene as of right.

Under Federal Rule of Civil Procedure 24(a), a party can intervene as of right when (1) the motion is timely made; (2) the would-be-intervenor has a “legally protectable interest” relating to the property or transaction which is the subject of the action; (3) that interest may, as a practical matter, be impaired or impeded as a result of the litigation; and (4) existing parties do not adequately represent the

applicant’s interests. Fed. R. Civ. P. 24(a); *see also Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015).

“Rule 24 is to be liberally construed.” *Brumfield v. Dodd*, 749 F.3d 339, 341 (5th Cir. 2014). Courts “should allow intervention where no one would be hurt and the greater justice could be attained.” *Sierra Club v. Espy*, 18 F.3d 1202, 1205 (5th Cir. 1994) (internal quotation marks omitted). “The inquiry is a flexible one, and a practical analysis of the facts and circumstances of each case is appropriate.” *Brumfield*, 749 F.3d at 342 (internal quotation marks omitted).

Novo Nordisk satisfies each of the criteria for intervention because its motion is timely, it has a significantly protectable interest in its commercial interests and reputation that will be impeded by OFA’s action, and FDA, a government defendant, cannot adequately represent Novo Nordisk’s commercial interests.

A. Novo Nordisk’s motion to intervene is timely.

Novo Nordisk’s motion to intervene—filed just seven days after Plaintiffs filed their complaint in this matter—is “timely.” Fed. R. Civ. P. 24(a). The timeliness analysis “is contextual.” *Espy*, 18 F.3d at 1205. The appropriate “gauge of promptness is the speed with which the would-be-intervenor acted when it became aware that its interests would no longer be protected by the original parties.” *Id.* at 1206. In assessing timeliness, courts generally consider “the length of time the movant waited to file, the prejudice to the existing parties from any delay, the prejudice to the movant if intervention is denied, and any unusual circumstances.” *Rotstain v. Mendez*, 986 F.3d 931, 937 (5th Cir. 2021); *see also Stallworth v. Monsanto Co.*, 558 F.2d 257, 264–66 (5th Cir. 1977).

Applying these factors, Novo Nordisk's motion to intervene is timely because it was filed soon after Plaintiffs filed their Complaint—indeed, before any defendant has filed a responsive pleading, and before any substantive action has taken place in this litigation other than the filing of the Complaint itself. This Court agreed to intervention under a similar timeline in *OFA*. *See Order Granting Intervention, OFA v. FDA*, No. 4:24-cv-00953-P, Dkt. 51 (N.D. Tex. Jan. 6, 2025). More generally, courts do not hesitate in finding that motions to intervene are timely under similar circumstances. *See, e.g., Espy*, 18 F.3d at 1206 (intervention three weeks after filing of lawsuit considered timely); *Edwards v. City of Houston*, 78 F.3d 983, 1000 (5th Cir. 1996) (intervention after forty-seven days considered timely); *John Doe No. 1 v. Glickman*, 256 F.3d 371, 376 (5th Cir. 2001) (intervention after one month considered timely). In fact, courts often grant motions to intervene that are filed at much later stages of the litigation. *See, e.g., Ass'n of Pro. Flight Attendants v. Gibbs*, 804 F.2d 318, 321 (5th Cir. 1986) (intervention five months after arbitration decision announced considered timely); *Diaz v. S. Drilling Corp.*, 427 F.2d 1118, 1125 (5th Cir. 1970) (intervention one year after completion of discovery and pretrial motions considered timely). *See generally Edwards*, 78 F.3d at 1001 (“[M]ost of [the Fifth Circuit’s] case law rejecting petitions for intervention as untimely concern motions filed after judgment was entered in the litigation.”).

Additionally, no party will suffer prejudice if this court allows Novo Nordisk to intervene. Novo Nordisk's participation would not require any deadlines to be modified. *See, e.g., Arkansas Project v. Shaw*, No. CIVA C-10-75, 2010 WL 2522415,

at *3 (S.D. Tex. June 17, 2010) (holding motion to intervene would not prejudice parties, given that it was filed before deadline for joinder of parties and no other essential deadlines had passed). *See also, e.g., Bishop v. Bostick*, No. 9:13-CV-82, 2014 WL 11486235, at *1 (E.D. Tex. May 15, 2014) (“[T]here is no question that this motion is timely, as no Order Governing Proceedings has yet been issued.”).

B. Novo Nordisk possesses a legally protectable interest in this action.

To intervene as of right, a movant must demonstrate a “legally protectable interest,” which is defined as an interest “that the law deems worthy of protection, even if the intervenor does not have an enforceable legal entitlement or would not have standing to pursue her own claim.” *Texas*, 805 F.3d at 659. Courts view this factor practically, with the “interest” test being “primarily a practical guide to disposing of lawsuits by involving as many apparently concerned persons as is compatible with efficiency and due process.” *Espy*, 18 F.3d at 1207.

Novo Nordisk has several concrete, legally protectable interests at stake in this litigation. To begin, “economic interests can justify intervention when they are directly related to the litigation.” *Wal-Mart Stores, Inc v. Tex. Alcohol Beverage Comm’n*, 834 F.3d 562, 568 (5th Cir. 2016); *see also Diaz*, 427 F.2d 1118, 1124 (“Interests in property are the most elementary type of right that Rule 24(a) is designed to protect.”). Novo Nordisk has a concrete economic interest because Novo Nordisk’s FDA-approved medicines, and the right to market and sell those medicines under FDA approvals held by Novo Nordisk without competition from unapproved and unsafe compounded drug products, are the “property or transaction which is the subject of the action.” Fed. R. Civ. P. 24(a). This action directly addresses semaglutide

injection medicines, a category of medicines that Novo Nordisk markets and sells, and upon which Novo Nordisk has spent billions of dollars in obtaining FDA approvals, including costs of sales and marketing.¹⁷ The removal of Novo Nordisk’s approved semaglutide injection medicines from the drug shortage list provides a concrete benefit to Novo Nordisk because it restores Novo Nordisk’s market position. See, e.g., *NextEra Energy Cap. Holdings, Inc. v. D’Andrea*, No. 20-50168, 2022 WL 17492273, at *3 (5th Cir. Dec. 7, 2022) (“Because [the law at issue] prospectively interferes with [proposed intervenors’] business opportunities, they have each demonstrated a legally protectable interest related to the subject matter of this case.”); *Espy*, 18 F.3d at 1207 (finding sufficient interest for intervention in case with U.S. Forest Service where movants had “legally protectable property interests in existing timber contracts that are threatened by the potential ban on even-aged management”).

Additionally, Novo Nordisk has a broader interest in the standards and procedures that govern the removal of a drug from the drug shortage list. The Fifth Circuit recognizes that “business owners have a right to intervene in lawsuits challenging the regulatory scheme that governs the profession.” *Wal-Mart*, 834 F.3d at 567. When a federal regulation would directly affect a company’s business, “the proffered violations and remedy confer on [movant’s] members a sufficient interest to

¹⁷ See Testimony of Lars Fruergaard Jørgensen, *supra* n.5 (Although it is “difficult to comprehensively quantify” the research and development costs for Novo Nordisk’s semaglutide medicines, based on a “conservative approximation,” those costs were “well over \$10 billion dollars.”).

intervene.” *Sierra Club v. Glickman*, 82 F.3d 106, 109 (5th Cir. 1996); *see also Crystal Clear Special Util. Dist. v. Lake*, No. 1:22-cv-01293, 2023 WL 4351509, at *5 (W.D. Tex. July 5, 2023), *rep. & recomm. adopted*, 2023 WL 4853407 (W.D. Tex. July 28, 2023) (finding legally protectable interest when company’s “ability to develop its property, which is the subject of the [public utility commission] hearing at issue, is impacted by the outcome of the decertification process” in the relevant statute).

Novo Nordisk has spent countless hours and billions of dollars bringing to market its revolutionary medicines. And, even though all doses of Novo Nordisk’s FDA-approved medicines are commercially available and Novo Nordisk’s supply meets or exceeds demand, Plaintiffs nevertheless seek to continue to profit from Novo Nordisk’s investment by selling unapproved drugs that undercut the safety and efficacy standards that Novo Nordisk’s FDA-approved medicines meet. If Plaintiffs continue compounding, patients will continue to be exposed to unapproved and potentially unsafe compounded “semaglutide” drugs rather than have the benefit of Novo Nordisk’s FDA-approved semaglutide injection medicines. Among other harms, patients may wrongly attribute quality problems and their injury from these unapproved compounded products to Novo Nordisk, harming the goodwill that Novo Nordisk has developed for its FDA-approved semaglutide injection medicines.

Finally, Novo Nordisk has a protected interest in protecting the confidential commercial information that it submitted to FDA that will likely be part of the administrative record. *See, e.g.*, FDA Declaratory Order at 1 (“Novo Nordisk’s submissions [to FDA] include detailed information and data regarding Novo

Nordisk's production and inventory of these drug products."). Congress recognizes that manufacturers must share confidential information with FDA during shortage situations, and it specified that such confidentiality must be maintained. See 21 U.S.C. §§ 356c(d), 356e(c)(2). Novo Nordisk has a right to participate in this litigation to protect the confidentiality of its information.

C. *Novo Nordisk's protectable interest may be impaired or impeded as a result of this proceeding.*

The impairment prong of Rule 24(a) looks to the practical consequences of denying intervention. *In re Lease Oil Antitrust Litig.*, 570 F.3d 244, 251 (5th Cir. 2009) ("[A] practical harm to Texas's property interest ... is sufficient to show impairment."). The Fifth Circuit also considers whether a judgment will "affect[] the movants, and [whether], because of the precedential effect of the district court's decision, an adverse resolution of the action would impair their ability to protect their interest." *Espy*, 18 F.3d at 1207.

Because the challenged agency action favors Novo Nordisk's protectable interests, those same interests would be impaired if Plaintiffs succeeded in their challenge. Under FDA's current interpretation of Section 503A, pharmacies would be allowed to produce compounded "semaglutide" products regularly and in "inordinate amounts" if semaglutide injection products remained on the drug shortage list. 21 U.S.C. § 353a(b)(1)(D). Under FDA's current interpretation of Section 503B, outsourcing facilities would argue that they are allowed to produce compounded products in massive quantities if semaglutide injection products were to remain on the drug shortage list. *Id.* § 353b(a)(2)(A)(ii).

The relief that Plaintiffs seek would directly impair Novo Nordisk’s ability to market and sell FDA-approved semaglutide injection medicines without competition from unapproved and unsafe compounded drugs. It would also allow Plaintiffs to make potentially dangerous compounded drugs, causing Novo Nordisk reputational harm if patients think that any ineffective or unsafe compounded drugs are produced by Novo Nordisk and incorrectly attribute those harms to it. Novo Nordisk therefore has legally protectable interests that may be impaired based on the outcome of this litigation. *See, e.g., Ross v. Marshall*, 426 F.3d 745, 757 n.46 (5th Cir. 2005) (“With respect to a potential intervenor seeking to *defend* an interest being attacked by a plaintiff in a lawsuit, we have observed that the intervenor is a real party in interest when the suit was intended to have a ‘direct impact’ on the intervenor.”).

D. The FDA cannot adequately protect Novo Nordisk’s commercial interests.

An applicant for intervention need only show that representation of its interest by an existing party “may be” inadequate. *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538–39 & n.10 (1972). The burden of making this showing “should be treated as minimal.” *Id.* at 538 n.10; *accord Berger v. N. Carolina State Conf. of the NAACP*, 597 U.S. 179, 196 (2022).

The presumption of adequate representation “when the would-be-intervenor has the same ultimate objective as a party to the lawsuit,” *Texas*, 805 F.3d at 661 (internal quotation marks omitted), is rebutted when a federal regulatory agency’s “attempt[] to represent the regulated parties” and its “statutory mandates to serve

the ‘public interest’ render its representation inadequate, *Kneeland v. Nat'l Collegiate Athletic Ass'n*, 806 F.2d 1285, 1288 (5th Cir. 1987).¹⁸

In this case, Novo Nordisk’s interests cannot be adequately represented by the existing parties for three reasons.

First, Plaintiffs’ position is adverse to Novo Nordisk’s, while the federal defendants have a broader, more general interest “in securing an expansive interpretation of executive authority [and] efficiently enforcing the [healthcare] laws.” *Texas*, 805 F.3d at 663. Although Novo Nordisk and FDA share a common goal of affirming FDA’s decision to remove semaglutide injection medicines from the drug shortage list based on the robust, objective, and reliable evidence showing that Novo Nordisk’s supply meets or exceeds demand and projected demand, the parties do not have the same ultimate objectives. *See Brumfield*, 749 F.3d at 345 (“Although both the state and the [proposed intervenors] vigorously oppose dismantling the voucher program, their interests may not align precisely,” so the “presumption does not apply”). As the Fifth Circuit has explained repeatedly, “[t]he government must represent the broad public interest, not just the economic concerns of [one] industry.” *Espy*, 18 F.3d at 1208. This makes it difficult for “federal regulatory agencies … to

¹⁸ A presumption of adequate representation also arises “when the putative representative is a governmental body or officer charged by law with representing the interests of the [proposed] intervenor” when that party is acting in a sovereign capacity. *Texas*, 805 F.3d at 661 (internal quotation marks omitted). This presumption does not apply to governmental agencies such as the FDA. *See, e.g., Entergy Gulf States Louisiana, L.L.C. v. U.S. Env't Prot. Agency*, 817 F.3d 198, 203 n.2 (5th Cir. 2016) (“[B]ecause EPA is a governmental agency and not a sovereign interest, a stronger showing of inadequacy is not required.”).

represent the regulated parties.” *Kneeland*, 806 F.2d at 1288. That is especially true in this case: FDA’s statutory mandate is to protect the broader public interest in health and safety of regulated drugs and to regulate those drugs based on their supply and demand. *See* 21 U.S.C. § 393(a)–(c) (defining FDA’s mission). By contrast, Novo Nordisk’s interest is to protect not only the safety of patients seeking semaglutide medicines, but also its reputation and commercial interests. The court need not “say for sure that the state’s more extensive interests [would] *in fact* result in inadequate representation, but surely they might [have], which is all that the rule requires.” *Brumfield*, 749 F.3d at 346 (emphasis in original).

Accordingly, courts have recognized that in many instances a government agency cannot adequately represent the interests of an intervenor if the agency has similar interests to a potential intervenor, but also has a statutory charge to pursue broader public-interest goals. *See, e.g., Trbovich*, 404 U.S. at 538–39; *JMCB, LLC, v. Bd. of Com. & Indus.*, No. CV 17-77-JWD-JCW, 2017 WL 6033407, at *10 (M.D. La. Dec. 5, 2017) (presumption of adequate representation did not apply when “the State Defendants [were] concerned with the administration of their tax program generally whereas [proposed intervenors] [were] directly invested in ensuring that these particular tax exemptions remain in effect”); *Abita Springs v. U.S. Army Corps of Eng’rs*, No. CV 15-0451, 2015 WL 13533518, at *2 (E.D. La. Sept. 25, 2015) (presumption did not apply when company’s interest was “narrower than the USACE, which is concerned with protecting the interest of the public in general,” whereas the company’s interest was “focused on protecting its individual investments”). Because

“the [FDA] like all government agencies, has a broader national interest, it is unlikely to afford [Novo Nordisk]’s more discrete and particularized interests the same primacy as would [Novo Nordisk] itself.” *Ouachita Riverkeeper v. U.S. Env’t Prot. Agency*, No. 3:14-cv-4495, 2015 WL 11120995, at *2 (N.D. Tex. June 15, 2015).

Courts frequently grant intervention as of right to industry participants in cases challenging FDA action, including but not limited to the *OFA* decision. *See, e.g.*, *Apotex Inc. v. U.S. Food & Drug Admin.*, 508 F. Supp. 2d 78, 80 & n.2 (D.D.C. 2007); *Eagle Pharms., Inc. v. Price*, 322 F.R.D. 48, 50 (D.D.C. 2017). Although the federal defendants’ and Novo Nordisk’s interests may coincide in defending the validity of FDA’s decision to remove semaglutide from the shortage list based on the overwhelming objective evidence demonstrating that Novo Nordisk’s supply meets or exceeds demand and projected demand, “their interests may not align precisely,” and the divergence between the federal defendants’ public interests and Novo Nordisk’s private interests supports Novo Nordisk’s right to intervene under Rule 24(a). *Brumfield*, 749 F.3d at 345.

Second, FDA may not agree with Novo Nordisk’s interpretation of Section 503A of the FDCA. Novo Nordisk believes that the plain text of Section 503A does not allow compounding pharmacies to manufacture copies of commercially available approved drug products regularly and in inordinate amounts—and that conclusion does not turn in any way on whether semaglutide injection products are currently on the shortage list. Specifically, subject to other laws and requirements, compounding pharmacies under 503A are only permitted to make “essentially a copy” of an FDA-

approved medicine in certain limited circumstances. *See* 21 U.S.C. § 353a(b)(1)(D). A drug product appearing on FDA's drug shortage list is not one of those limited circumstances. Unlike Section 503B of the FDCA, Section 503A makes no mention of drug shortages. *Compare* 21 U.S.C. § 353b(a)(1)(2)(A)(ii), *with* 21 U.S.C. § 353a. Rather, it has a narrow exception to the “essentially a copy” restriction when a medicine is not “commercially available.” 21 U.S.C. § 353a(b)(1)(D). Commercial availability is not the same as a drug shortage, as confirmed by statutory text and legislative history. Plaintiffs have alleged that FDA disagrees and has chosen to allow compounding pharmacies to mass-manufacture copies of commercially available drugs if they are on the shortage list. *E.g.*, Compl. ¶ 20. If Plaintiffs are correct, no party in this litigation adequately represents Novo Nordisk’s interest in seeing the appropriate application of Section 503A for semaglutide injection products.

Finally, FDA may not fully appreciate the extent to which Novo Nordisk’s confidential information needs to be protected. Novo Nordisk submitted confidential commercial information to FDA when the agency was evaluating whether or not to remove semaglutide injection medicines from the drug shortage list. FDA will likely submit that information to the Court as part of the administrative record, and does not have the same vested commercial interest as Novo Nordisk in ensuring that information remains confidential. Novo Nordisk should be allowed to intervene to protect its confidential commercial information.

II. Alternatively, Novo Nordisk should be granted permission to intervene under Rule 24(b).

Federal Rule of Civil Procedure 24(b)(1) provides that “[o]n timely motion, the court may permit anyone to intervene who ... has a claim or defense that shares with the main action a common question of law or fact.” Rule 24(b)(3) adds that “[i]n exercising its discretion, the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties’ rights.” Courts construe “claim or defense ... liberally” to cover any “interest or remedy recognized at law.” *United States ex rel Hernandez v. Team Fin., LLC*, 80 F.4th 571, 577 (5th Cir. 2023) (citations omitted).

Novo Nordisk meets the requirements for permissive intervention. In particular, the defenses that the federal defendants and Novo Nordisk are likely to raise will involve common questions of law or fact. For example, Novo Nordisk’s opposition to the relief sought by Plaintiffs will implicate the standards imposed by the FDCA and the Administrative Procedure Act, as well as the factual record that informed FDA’s application of those statutes in removing semaglutide injection medicines from the drug shortage list. In addition, as shown above, Novo Nordisk has a substantial interest in the outcome of this litigation, and Novo Nordisk’s intervention would vindicate “[t]he very purpose of intervention,” which is “to allow interested parties to air their views so that a court may consider them before making potentially adverse decisions.” *Brumfield*, 749 F.3d at 345. Finally, Novo Nordisk has moved for leave to intervene in a timely manner, such that granting Novo Nordisk’s

motion would not delay the disposition of this case or prejudice the original parties in any way.

Thus, if the Court does not allow Novo Nordisk to intervene as of right under Rule 24(a), it should grant Novo Nordisk permissive intervention under Rule 24(b) in the exercise of its sound discretion.

CONCLUSION

This action challenges FDA's decision to remove semaglutide injection medicines from the drug shortage list. Novo Nordisk, the only company who markets FDA-approved semaglutide injection medicines, has a protectable interest in the outcome of this action and has timely moved to intervene. As in *OFA v. FDA*, No. 4:24-cv-00953-P (N.D. Tex.), this Court should grant the motion for intervention.

March 3, 2025

Respectfully submitted,

/s/ Trevor Carolan

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CERTIFICATE OF SERVICE

I hereby certify that, on March 3, 2025, I caused the foregoing document to be filed with the Clerk of the Court of the United States District Court for the Northern District of Texas using the Court's CM/ECF system.

/s/ Trevor Carolan
Attorney for Novo Nordisk Inc.